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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
08/888,202	07/07/97	PIMENTEL J	pak

HM12/0203

JULIO L PIMENTEL
3206 WINDGATE DRIVE
BUFORD GA 30519

EXAMINER	
UNGAR, S	
ART UNIT	PAPER NUMBER
1641 1642	8

DATE MAILED: 02/03/99

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☐ Responsive to communication(s) filed on 11/16/98

☑ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), ~~or thirty days,~~ whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☑ Claim(s) 1-4, 8, 11, 17-22 & 25-35 is/are pending in the application.
Of the above, claim(s) / is/are withdrawn from consideration.
☐ Claim(s) _____ is/are allowed.
☑ Claim(s) 1-4, 8, 11, 17-22 & 25-35 is/are rejected.
☐ Claim(s) _____ is/are objected to.
☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
☐ The specification is objected to by the Examiner.
☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.
☐ received in Application No. (Series Code/Serial Number) _____.
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of Reference Cited, PTO-892
☑ Information Disclosure Statement(s), PTO-1449, Paper No(s). 7
☐ Interview Summary, PTO-413
☐ Notice of Draftperson's Patent Drawing Review, PTO-948
☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

★ U.S. GPO: 1998-404-496/40017

1. The Amendment filed November 16, 1998 (Paper No. 6) in response to the Office Action of August 18, 1997 (Paper No. 5) is acknowledged and has been entered. Previously pending claims 1, 14 and 25 have been amended and new claims 26-35 have been added. Claims 1-4, 8, 11, 17-22 and 25-35 are currently being examined.

2. It is noted that, due to a typographical error, the acknowledgment of the admission on the record that the species of Section 15 of Paper No. 5 are obvious variants of each other was omitted. Because of this admission, the election of species requirement in section 15 of Paper No. 5 is withdrawn.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. The following rejections are being maintained:

Claim Rejections - 35 USC § 103

5. Claims 1-4, 8, 11, 14, 17-22 remain rejected under 35 USC 103 for the reasons previously set forth in Paper No. 5, Section 9, pages 4-8.

Applicant argues that (a) there is no motivation to one of ordinary skill in the art to combine the teachings of these references in order to arrive at the Applicant's claimed invention, (b) the lack of motivation to one of ordinary skill in the art to combine the teachings can be demonstrated by considering each of the references in turn and (c) given the long period of time between the publication dates of the references, one would certainly have combined the teachings in the proposed manner prior to the applicant. The arguments have been noted but have not been found persuasive (a) for the reasons previously set forth, drawn to motivation on

page 8 of Paper No. 5, (b and c) Applicant has argued and discussed the references individually without clearly addressing the combined teachings. It must be remembered that the references are relied upon in combination and are not meant to be considered separately as in a vacuum. It is the combination of all of the cited and relied upon references which made up the state of the art with regard to the claimed invention. Applicant's claimed invention fails to patentably distinguish over the state of the art represented by the cited references taken in combination. In re Young, 403 F.2d 754, 159 USPQ 725 (CCPA 1968); In re Keller 642 F.2d 413,208 USPQ 871 (CCPA 1981) further, it is not possible to determine that the references have not been previously combined.

New Grounds of Rejection

Claim Rejections - 35 USC § 102

6. Claim 34 is rejected under 35 U.S.C. § 102(b) as being anticipated by Murase et al (Atherosclerosis, 1981, 39:293-300).

The claim is drawn to a method of transferring antibodies from an animal to other animals comprising administering to said animal an antibody containing substance derived from a producer animal wherein said producer animal had been immunized with lipase wherein lipase regulates a biochemical process in the gastrointestinal tract.

Murase et al teaches a method of transferring antibodies from a laboratory rabbit immunized with lipase to rats. It was well known in the art at the time the invention was made that lipase regulates biochemical processes in the gastro-intestinal tract.

Applicant's arguments drawn to rejection of claim 25 are relevant to the instant rejection.

Applicant argues that the lipase of Murase et al is HTGL and not pancreatic lipase which regulates a biochemical process in the gastrointestinal tract and further states that according to Murase et al, the physiological function of the enzyme in lipoprotein metabolism is still unclear and that the reference does not disclose that HTGL regulates biochemical processes in the gastrointestinal tract, nor does it disclose that this specific enzyme occurs in the gastrointestinal tract. The argument has been noted but has not been found persuasive because the claimed lipase appears to be the same as the broadly claimed prior art lipase, absent a showing of unobvious differences. The office does not have the facilities and resources to provide the factual evidence needed in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is on the applicant to prove that the claimed product is different from that taught by the prior art and to establish patentable differences. See In re Best 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989).

Claim Rejections - 35 USC § 103

7. Claims 26-33 are rejected under 35 U.S.C. § 103 as being unpatentable over US Patent No. 4,598,089 in view of Moloney (Livestock Production Science, 1995, 42:239-245), Flint (Proceedings of the Nutrition Society, 1992, 51:433-439), Ohkaru et al (Clin. Chim. Acta (1989) 182:295-300) or JP 02150294, US Patent

No. 5,585,098, US Patent No. 5,080,895 for the reasons disclosed in Paper No. 5, Section 9, pages 4-8 drawn to claims 1-4, 8, 11, 14, 17-22

The claims are drawn to a method of decreasing fat absorption in mammals by feeding an avian antibody that binds lipase thereby inhibiting its activity in the gastrointestinal tract wherein said antibody is produced against an animal antigen and is produced in avian eggs, obtained from unfractionated whole eggs wherein the antibody is freeze dried, orally fed in a variety of forms, wherein decreased fat absorption is due to a deceased lipase activity whereby fat is extracted and not absorbed in the gastrointestinal tract and further drawn to the method wherein the antibodies are obtained from the yolk of an egg without fractionation thereof, by fractionation thereof, wherein the antibody is first spray dried, encapsulated, wherein prepared foods are identified, wherein the antibody is orally fed in liquid form, in compressed tablet form.

The claims are obvious for the reasons previously disclosed and because of Applicant's admission on the record that the newly added embodiments are obvious variants of limitations recited in the rejected claims.

8. Claims 25, 34 and 35 are rejected under 35 U.S.C. § 103 as being unpatentable over US Patent No. 4,598,089 in view of Moloney, Flint, Ohkaru et al 182:295-300) or JP 02150294, US Patent No. 5,585,098, US Patent No. 5,080,895.

The claims are drawn to a method of transferring to a first animal antibodies from a second animal, immunized with lipase, in order to modify a biochemical process wherein the antibodies are orally administered, wherein the lipase is pancreatic lipase.

US Patent No. 4,598,089 sets forth as previously disclosed but does not teach a method of orally transferring to a first animal antibodies from a second animal in order to modify a biochemical process wherein the second animal has been immunized with lipase wherein said lipase regulates a biochemical process in the gastrointestinal tract wherein said animal has been immunized with pancreatic lipase.

Moloney, Flint, Ohkaru et al, JP 02140294, US Patent No. 5,080,895 teach as set teach as set forth previously. US Patent No. 5,858,098 teaches as set forth previously and further teaches that antibodies are produced by immunization of a hen with the antigen, a specific antibody against the antigen is produced within the body of the hen and an egg laid by the hen contains the specific antibody and the presence and the titer level of the specific antibody against the antigen in the hen and in eggs of the hen can be confirmed by a number of method (col 6, lines 27-36).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to generate and screen for an antibody that inhibits pancreatic lipase in hens using the pancreatic lipase of Ohkare et al or JP 02150294 as the starting antigen in the basic method of US Patent No. 5,585,098 because US Patent No 5,585,098 teaches the successful production of antibodies in hens for oral administration to cattle in animal feed and because both Ohkare et al and JP 02150294 teach that their antibodies hinder lipase activity. The person of ordinary skill in the art would have been motivated to produce inhibitory monoclonal antibodies specific for pancreatic lipase using the method of US Patent No. 5,585,098 with a reasonable expectation of success. Further, it would have been

prima facie obvious to one of ordinary skill in the art at the time the invention was made to substitute the antibody of the combined references for the tetrahydrolipstatin of US Patent No. 4,598,089 because both molecules inhibit pancreatic lipase (which regulates a biochemical process in the gastrointestinal tract) and because Moloney suggests the identification of specific antigenic determinants to be used in immunological methods to decrease fat content in meat and because Flint specifically suggests that one strategy of immunomodulation of adiposity is the immunoneutralization of gastrointestinal substances that have direct lipogenic effects on adipose tissues. Further, it would have been *prima facie* obvious to administer antibodies generated in a hen using the prior art antigen of against lipase in oral form because US Patent No. 5,585,098 teaches the successful oral administration of chicken yolk immunoglobulins to cattle in feed. One of ordinary skill in the art would have been motivated to substitute the antibody of the combined references for the tetrahydrolipstatin of US Patent No. 4,598,089 because both molecules are inhibitors of pancreatic lipase and because Moloney and Flint teach the importance of immunological manipulation of fat deposition and adiposity. One of ordinary skill in the art would have been motivated to orally administer the antibodies of the combined prior art because US Patent No. 5,080,895 teaches that oral administration of avian antibodies was desirable in the art.

9. All other objections and rejections recited in Paper No. 5 are withdrawn.

10. No claims allowed.

11. Applicant's amendment necessitated the new grounds of rejection.

Accordingly, **THIS ACTION IS MADE FINAL**. See M.P.E.P. § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (703) 305-2181. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paula Hutzell, can be reached at (703) 308-4310. The fax phone number for this Art Unit is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Effective, February 7, 1998, the Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1640.

Susan Ungar
January 25, 1999

PAULA K. HUTZELL
SUPERVISORY PATENT EXAMINER